February 26, 2016

The Honorable Ron Wyden
United States Senate
221 Dirksen Senate Office Building
Washington DC 20510

The Honorable Charles Grassley
United States Senate
135 Hart Building,
Washington, DC 20510

RE: Wyden Grassley Sovaldi Report Feedback

Dear Senator Wyden and Senator Grassley,

On behalf of the Hepatitis Foundation International (HFI), we are pleased to be able to share HFI's comments on the Wyden Grassley Sovaldi Report on Gilead's pricing issue. HFI is a 501(c) 3 non-profit organization established in 1994 to eradicate viral hepatitis for 550 million people globally. HFI is also dedicated to increasing and promoting health and wellness, as well as, reducing the incidence of preventable liver-related chronic diseases and lifestyles that negatively impact the liver. Some of these diseases include obesity, diabetes, hepatitis, substance abuse, HIV/AIDS, cardiovascular disease, fatty liver disease and liver cancer. We implement our mission through our touchstones to educate, prevent, serve, support, and reach well over 5 million patients and health care professionals annually. Below you will find HFI's feedback to the investigation report

1) What are the effects of a breakthrough, single source innovator drug on the marketplace?

A critical issue concerning innovation of drugs in the healthcare market is the high-and at times astronomically high-costs. Financing drug treatment innovation has led to payers limiting drug utilization, increasing cost-sharing, leading the government to intervene when prices became financially burdensome or inaccessible. This effect of drug innovation pricing in the market threatens public health outcomes and budgets of the country's healthcare system. Over $87 billion are spent annually on specialty drugs as a result of both pharmaceuticals and healthcare payers unwilling to compromise their stake in benefitting from drug innovation. For an individual patient, costs for these costs can range from a few thousand to over a 100,000 every year. Diseases with smaller population face higher burden of drug cost.

There are many high priced drugs on the market that target rare disease with a smaller patient population, however up to 150 million people are currently infected with hepatitis C and about 500,000 are dying each year from related liver conditions, according to the World Health Organization. Furthermore, the majority of those infected with hepatitis C live in middle-income countries in the Middle East and Central and East Asia, putting the drug's high price out of reach.

The approval of Zepatier from Merck may force Gilead Sciences to drop the price of Harvoni and Sovaldi (in combination with Olysio). Zepatier is priced at $54,600 for a 12-month treatment, but does not treat as many genotypes of hepatitis as Sovaldi and Harvoni.

2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of new treatment regimen?

Pharmaceutical companies determine the wholesale acquisition cost (WAC) of a drug and pharmacy benefit managers (PBMs) negotiate contracts with pharmaceutical companies on behalf of the health insurance companies. Negotiations for drug prices are considered confidential business contracts between the payer (insurance companies) and the provider (pharmaceuticals), resulting in no transparency regarding the actual price paid for hepatitis C drugs. Insurers, government agencies, and PBMs rarely negotiate to pay the much-publicized WAC. However, the negotiations of pricing and cost-structure for pharmaceutical products in the United States are not transparent, and therefore it is challenging to assess the true cost and cost-effectiveness of HCV drugs.

Subsequently, the viral hepatitis surveillance system in the United States is highly fragmented and lacks sufficient information. As a result, surveillance data does not provide accurate estimates of the current burden of disease which creates a barrier for program planning and evaluation. There is not enough information to allow policy-makers to allocate sufficient resources to viral hepatitis prevention and control programs. The federal government has provided limited resources—in the form of guidance, funding, and oversight—to local and state health departments to perform surveillance for viral hepatitis. An accurate estimate of the current burden of disease can assist provide payers with a more realistic estimate of patient volume.

3) What role does the concept of 'value' play in this debate, and how should an innovative therapy's value be represented in its price

Gilead said in a statement to Bloomberg BNA that it stands behind the pricing of its therapies because of the benefit they bring to patients and the significant value they represent to payers, providers and the entire health-care system by reducing the long-term costs associated with managing chronic hepatitis C virus (HCV). The cost of Sovaldi has the potential to pay for itself many times over in the years following a successful round of treatment. A liver transplant can cost upwards to $250,000 and more than $500,000 in follow-up care every year of the patient's life. Sovaldi is a high-value prescription, in that it can essentially cure hepatitis and save insurance companies thousands of dollars. However, most insurance companies look at it as not only a high cost treatment, but as something that is being used at the cost of other treatments. However, hepatitis drug costs are not comparable to prices for other treatments. People diagnosed with diabetes incur average medical expenditures of about $13,700 per year, $7,900 of which are spent directly on diabetes treatment4. The average cost over the lifetime of a patient depends on

the age at which the patient was diagnosed and therefore varies from type 1 to type 2 and from person to person. The average short term cost for stroke patients for 90 days of treatment is from $15,000 to $35,000. The cost for treatment acute coronary syndrome, which includes heart attacks and chest pain, is $8,170 annual out-of-pocket expenses, $625 of which is going towards pharmaceuticals. A study done by Stacie B. Dusetzina, along with colleagues from UNC, Harvard and the Dana-Farber Cancer Institute, found that the out-of-pocket cost of Gleevec ranged from nothing to 4,792 for a 30-day supply of the medicine6. The out-of-pocket cost of arthritis medication can range from $5 to $6,660 depending on insurance and copayment rates. A SAMHSA Survey on Drug Use and Health estimated the out-of-pocket costs for individuals that seek out-patient mental health treatment to be $100-$5,000 per year. From this data, it is clear that the cost of hepatitis drugs are not at all comparable to the cost of treatment for other chronic diseases.

4) What measures might improve price transparency for new higher-cost therapies while maintain incentives for manufacturers to invest in new drug development?

Insurance related costs are typically hidden in complicated policy statements that are difficult to read. Oftentimes treatment centers shy away from displaying the total cost of services because of the fear of "sticker shock". In order to improve transparency, insurance companies should create a breakdown of all costs that is easily understood. This cost breakdown would include the tiers of medication, along with co-pay and a real-world example of what an individual has paid in the past. The costs of therapies, including diagnostics, imaging, and medications, along with other fees, should be made apparent to patients. Physicians should initiate a conversation shortly after diagnosis about the cost of treatment, as to prepare patients for billing while receiving treatment.

5) What tools exists, or should exists, to address the impact of high-cost drugs and corresponding access restriction, particularly on low-income populations and state Medicaid programs?

If an insurance company places most or all drugs that treat a certain condition on the highest cost tiers, that plan effectively discriminates against and discourages the treatment of individuals who have those chronic diseases. More effective measures must be taken to enforce the provisions built into the Affordable Care Act to prohibit insurers from discriminating against people on the basis of health condition. Effective measures should also be implemented to make certain that HHS will monitor health plans sold on the public exchange to ensure they remain compliant and meet the ACA standards.

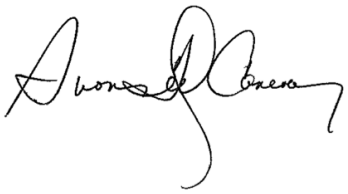
Subsequently, price spikes in the generic drug market have become a huge risk to public health and are resulting in less patient access to affordable healthcare. The Healthcare Supply Chain Association works to lower the costs and the increasing competition in the healthcare marketplace. The FDA should be authorized to expedite review and approval of new generic drugs. This will result in the elimination of price spikes and will help ensure that everyone has access to critical medications.

One solution for state restrictions for accessibility to high-cost drugs is to carve these treatments out-in this case HCV drugs. Proponents for this solution point out that 'carving' enables states to access rebates and increase savings as a result of the estimated changes. However this applies to overall drug utilization, not just for prices alone. Others have been skeptical, citing that MCO-managed pharmacies, not carve-

outs, lower drug utilization costs. Still, some states in the past (such as Pennsylvania) have reported lower costs in overall drug utilization after implementing carve outs.

The Hepatitis Foundation International looks forward to assisting further as this process continues. Please do not hesitate to contact me directly at ifcameron@hepatitisfoundation.org or by telephone at (301)-565-9410 if we can be of further assistance.

Sincerely,



Ivonne Fuller Cameron
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